

BEST AVAILABLE COPY



JK 103/791

10/535651

RECEIVED	
19 JAN 2004	
WIPO	PCT

Kongeriget Danmark

Patent application No.: PA 2002 01789

Date of filing: 19 November 2002

Applicant:
(Name and address) Rhinometrics A/S
Industrivej 9
DK-3550 Lynge
Denmark

Title: Device for measuring in bodily cavities.
(Indretning til måling i kropskaviteter)

IPC: A 61 B 5/107; A 61 B 5/085; A 61 B 8/12

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

04 December 2003


Henrik Grye Skou




PATENT- OG VAREMÆRKESTYRELSEN

Patentansøgning

Modtaget
19 NOV. 2002

PVS



Patent- og
Varemærkestyrelsen
Erhvervsministeriet

Helgeshøj Allé 81
2630 Taastrup

Tlf. 43 50 80 00

Fax 43 50 80 01

Postgiro 8 989 923

E-post pvs@dkpto.dk

www.dkpto.dk

Læs venligst vejledningen til de enkelte punkter

2. Ansøgers fuldmægtigs referencenr. P-2002-023

3. International indleveringsdag:

☐ Kapitel I

Internationalt ansøgningsnr.:

☐ Kapitel II

4. Ansøger (fulde navn, adresse og evt. CVR-nr.): 21 11 33 79

☐ Flere ansøgere på bagsiden

Rhinometrics A/S

Industrivej 9

3550 Lyngby

Telefon:

Telefax:

5. Fuldmægtig (navn og adresse):

Mikael T. Christensen

c/o Oticon A/S

Strandvejen 58

2900 Hellerup

Telefon: 39177100

Telefax: 39277900

6. Opfinder (fornavn, efternavn, adresse):

Steen B. Rasmussen

Rhinometrics A/S

Industrivej 9

3550 Lyngby

6a. Opfinder (fornavn, efternavn, adresse):

☐ Flere opfindere på bagsiden

Peter Foged Christensen

Rhinometrics A/S

Industrivej 9

3550 Lyngby

7. Opfindelsens benævnelse:

Device for measuring in bodily cavities

(Indretning til måling i kropskaviteter)

8. Prioritetspåstand(e):

☐ Flere prioritetspåstande på bagsiden

Dato

Land

Nr.

Dato

Land

Nr.

Dato

Land

Nr.

9. ☐ Ansøgningen omfatter deponering af en prøve af biologisk materiale, som angivet i patentlovens § 8a, stk. 1.

10. ☐ Ansøgningen omfatter en sekvensliste.

11. ☐ Ansøgningen er fremkommet ved deling eller udskillelse

Stamansøgningens nr.:

Ansøgt løbedag:

13. ☐ Ansøgningen er tidligere
indleveret pr. telefax den:

14. Dato og underskrift:
19. November 2002

[Handwritten signature]

15. Behandling af fremmed-
sproget ansøgning mm. ønskes

☐ norsk

☐ svensk

☒ engelsk

1.1-marts

PA 02.11.2002

19 NOV. 2002

Modtaget

1
TITLE

Device for measuring in bodily cavities

5 BACKGROUND OF THE INVENTION

The present invention relates to the examination and measurement of constrictions or passages in cavities by means of acoustic reflectometry using a device comprising an electric signal source, a catheter to be introduced through an entrance to a cavity, a first
10 transducer for transfer of an activation signal from the signal source to and through the catheter, a second transducer for reception of response signals from the catheter, the first and second transducers being connected with the, and a computer adapted for analysis of the response signals in relation to the activation signal.


15 For examination and measurement of blockings, deformations, movements etc. in various human and animal cavities, e.g. pharynx, larynx and other air and alimentary passages, urinary passages, arteries etc. various methods are known.

From US 5823965 a device and a method are known, which comprise a catheter with a
20 flexible measuring zone. The device may comprise means for establishing a positive pressure with the purpose of dilating the flexible measuring zone.

SUMMARY OF THE INVENTION

25 The invention aims towards providing improvement in the measuring accuracy in such devices.

According to the invention this may be achieved by means of a device as defined in claim 1. The flexible and essentially non stretchable catheter with the proper
30 circumferential dimensions may when inflated adapt more closely to the sidewall of the bodily cavity without deforming this and hence give rise to a more accurate information of the geometry of the bodily cavity.



The catheter may be manufactured from a material chosen among ... combinations of such materials and other materials with similar mechanical properties. The catheter is then manufactured with a material thickness between 10 and 100 μm , preferably between 10 and 50 μm .

5

The invention further relates to a catheter for use in connection with a device according to the invention. This is defined in claim 5.

10

Further the invention relates to a method for establishing a measuring scenario. This is defined in claim 8.

15

In preferred embodiments of the method, the cavity is an organic cavity, e.g. the respiratory passages, the blood or lymph tracts, the alimentary canal, or the urinary system or sections thereof of an animal or a human body.

Other features and advantages of the present invention will become apparent from the following description of embodiments of the invention, which refers to the accompanying drawings.

20

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of the basic lay-out of the device according to the an embodiment of invention;

25

FIG. 2 is a perspective drawing of part of the catheter, at the spot where the measurement is made;

FIG. 3 is a perspective drawing of part of the catheter in another embodiment of the invention;

30

FIG. 4 is a sectional view of the catheter according to FIG. 3 in a sectional plane at right angles to the axis of the catheter;

FIG. 5 illustrates the placing of a catheter in the upper air passages with a patient being examined for tongue-fallback;

- 5 FIG. 6 illustrates the placing of a catheter in the upper air passages with a patient being examined for stertorous respiration.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

10

FIG. 1 shows the basic lay-out of the device according to the invention.

As seen in FIG. 1, there is shown a catheter 1, the design of which will be explained below. At its proximal end A, the catheter 1 of a manner known per se, not illustrated, is
15 connected to auxiliary equipment used for inserting the catheter in, e.g., the air passages of a patient, through the mouth or the nostrils, or in the urinary system or an artery. The distal end of the catheter B, which after insertion, will be present in the cavity of the patient who undergoes an examination.

20 An electronic signal generator 2 is adapted to give an activation signal to a transducer 3 connected to the catheter 1. The signal generator 2 delivers the same signal to a signal analysis processor 4. A transducer 5 is connected to the catheter 1. When an excitation signal is transferred from the signal generator 2, via the transducer 3, to the interior of the catheter 1, this signal will propagate in the catheter, on to the distal end of the
25 catheter, from where a response signal is sent back and received by the transducer 5 and from there led to the signal analysis processor 4. A pump is provided for supplying a pressure to the catheter to inflate this. The pump is preferably controllable to vary the pressure supplied. It is a possibility to fill the catheter with a liquid for provide other conditions for the acoustic transmission. A further transducer may be provided for
30 obtaining pressure data.

The signal analysis processor 4 is connected to a computer 6 by means of which it is possible on a screen 7 to present an image, which illustrates the results of the

examination and measurements made.

The transducer 3 can be an arbitrary type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezo-electric transducer, etc. Its task is to
5 transform the electronic signal from the signal generator 2 into an excitation signal in the interior of the catheter 1.

The transducer 5 can also be of the above mentioned arbitrary type, e.g. a microphone, the purpose of which is to receive an acoustic response signal from the distal end of the
10 catheter and to transform this response signal into an electric signal which is led to the signal analysis processor 4.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique known per se.
15

A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is located in the lumen 11.

20 FIG. 5 illustrates the use of the catheter in order to determine the position of and measure the so-called tongue fallback with a patient, e.g. the situation where the patient's tongue narrows the upper air passages.

Here the catheter has been introduced through the nostrils and into the air passage. Part
25 of the catheter is compressed by the rear end of the tongue in the zone D.

FIG. 6 shows the situation illustrated in FIG. 5 as well as the situation where said soft parts of the palate compress the catheter in the zone E.

30 FIG. 6 illustrates the situation where a patient is to be examined for vibrations in the soft parts of the palate, e.g. typically stertorous respiration. The vibrations in the zone E will influence at least one of the outer chambers of the catheter and the measurement equipment can carry out the positioning and measurement.

Obviously medical or surgical considerations decide the choice of the inner and outer dimensions of the catheter which is the reason why the catheter is manufactured in different sizes (and lengths too), while the measurement equipment decides the upper
5 frequency limit, if a transient signal is used, as well as the other physical parameters.

A particular example of the use of the invention has already been mentioned.

Exact examinations of persons, whose air passages are blocked during their sleep and
10 who can be described as having stertorous respiration, are naturally very difficult and through the ages many failed corrective operations have been made on these patients.

This is the reason why equipment which acoustically registers the stertorous respiration does not activate an alarm with sufficient security, as the non-occurrence of a "snoring
15 sound" is either due to a quiet, steady respiration with a low regular flow, which is all right, or the air passages being blocked for a long time. This is where the risk lies.

An internal measurement has the advantage that the patient is not awakened during the measurements by the excitation signal and at the same time the measurements are not
20 influenced to a large extent by the high tone sound spectrum of the snoring sounds.

The measurement probe itself is very easy to introduce ambulatory into the patient's nose before the night, in cooperation with a doctor or a nurse.

25 A correct "tightening" through the nose happens automatically due to the reflexory swallowing, and a connection (transducer/microphone part) at the end which projects out of the nose can be made without problems.

It should also be noted that the measurement equipment (hardware/software) which
30 adequately makes the measurements in each chamber and during the measurements changes the static pressure in each chamber can also concurrently give information about the elasticity of the tissue giving counter-pressure to the surface of the chambers.

By establishing a pressure in the catheter and a concurrent supply of acoustic energy in the infrasound band up to 200 Hz in the lumen and the chambers and a synchronization of this infrasound signal with the acoustic rhinometry (reflectometric) measurements, it is possible to obtain valuable information about the elasticity in the walls to which the catheterwall establishes a contact during the various pressure conditions.

Considering that these kinds of transducers, e.g. a piezoelectric transducer function in both directions, e.g. being applied an electric voltage in order to give a pressure signal, or receiving a pressure signal and give an electric signal, it is obvious that instead of two transducers 3 and 5 in FIG. 1 it is in principle possible to use one single transducer, in which case the signal generator 2 should be electronically designed in such a way that, when operated from the analysis unit 4 and the computer 6, it firstly gives a transient signal and then transfers the response signal to the analysis unit. If a random or a pseudo-random signal is used as excitation signal, emitted continuously in the measurement period, two separate transducers will be used, as shown in FIG. 1.

It should also be added that the invention also offers the possibility of making prostate or uterus examinations and other examinations in bodily cavities like the urinary passage etc.

CLAIMS

1. A device for measuring in bodily cavities, the device comprising catheter with a flexible and essentially not stretchable measuring part having a circumferential dimension essentially sufficient to establish circumferential contact with the bodily cavity in an area of interest, a pump in connection with the catheter and adapted to provide a positive pressure to the catheter to inflate the catheter so as to essentially fill out the bodily cavity in the area of interest essentially without deforming the bodily cavity.
2. A device according to claim 1, where the catheter is manufactured from a material chosen among polyetan, polyethylen and other materials with similar mechanical properties or combinations of such materials.
3. A device according to claim 1, where the catheter is manufactured with a material thickness between 10 and 100 μm , preferably between 10 and 50 μm .
4. A device according to claim 1, where the pump is controllable to vary the pressure supplied to the catheter.
5. A catheter for use in a device for measuring in bodily cavities, the catheter comprising a flexible and essentially not stretchable sidewall having a circumferential dimension essentially sufficient to establish circumferential contact with the bodily cavity in an area of interest, the catheter being adapted for connection with a pump for providing a positive pressure to the catheter to inflate the catheter so as to essentially fill out the bodily cavity in the area of interest essentially without deforming the bodily cavity and essentially without stretching the catheter sidewall.
6. A device according to claim 5, where the catheter is manufactured from a material chosen among polyetan, polyethylen and other materials with similar mechanical properties or combinations of such materials.



7. A device according to claim 5, where the catheter is manufactured with a material thickness between 10 and 100 μm , preferably between 10 and 50 μm

5 8. A method for establishing a measuring scenario in a bodily cavity, the method comprising introducing a catheter into the cavity and inflating the catheter so as to essentially fill out an area of interest in the bodily cavity essentially without stretching the catheter material and essentially without deforming the bodily cavity and further establishing a reflectometric measurement in the catheter.

10

9. A method according to claim 8, comprising varying the pressure supplied to the catheter.

ABSTRACT

The invention relates to a device for measuring in bodily cavities, the device comprising catheter with a flexible and essentially not stretchable measuring part having a
5 circumferential dimension essentially sufficient to establish circumferential contact with the bodily cavity in an area of interest, a pump in connection with the catheter and adapted to provide a positive pressure to the catheter to inflate the catheter so as to essentially fill out the bodily cavity in the area of interest essentially without deforming the bodily cavity.

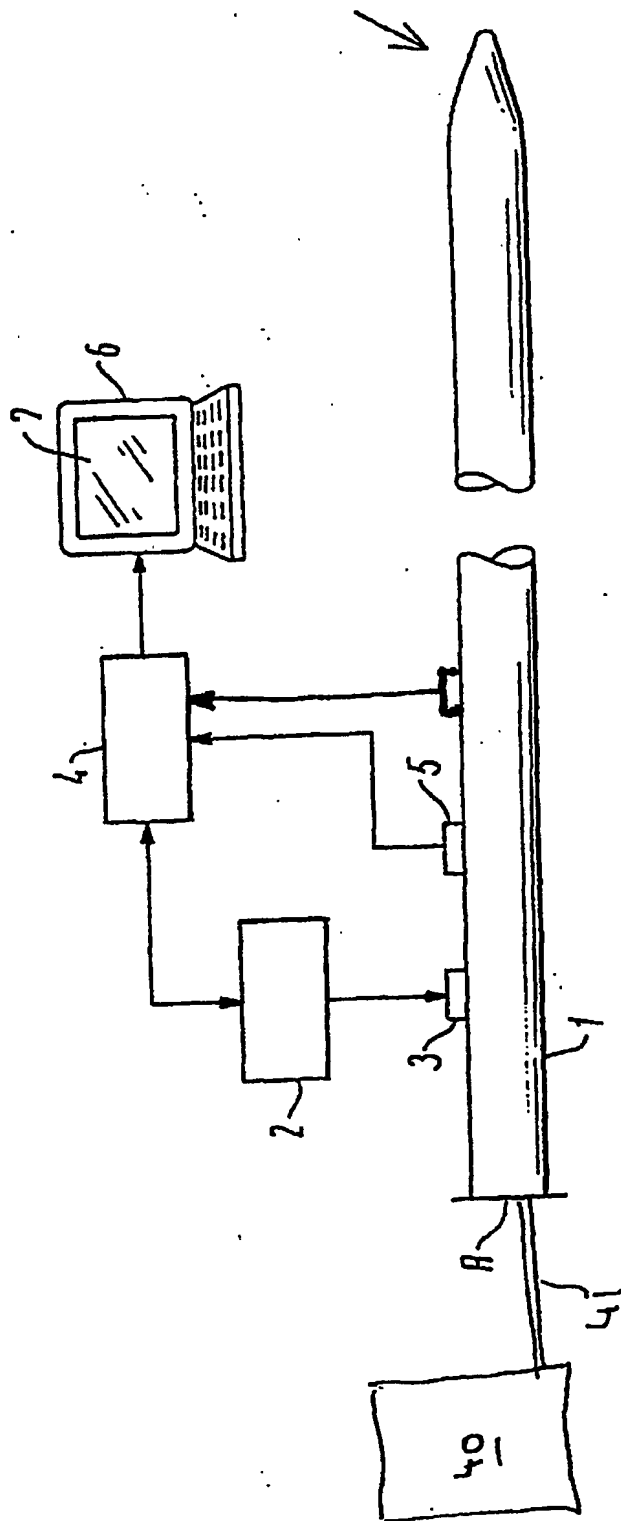


FIG. 1

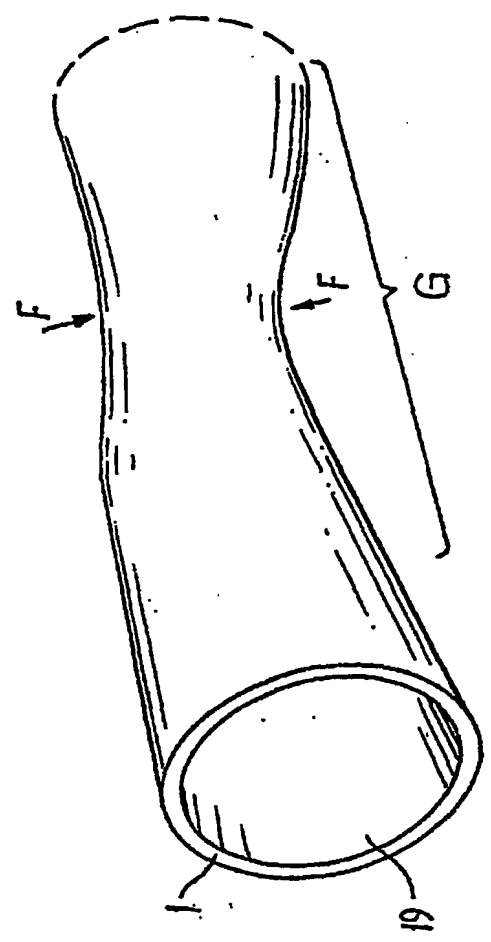


FIG. 2

19 NOV. 2002

Modtaget

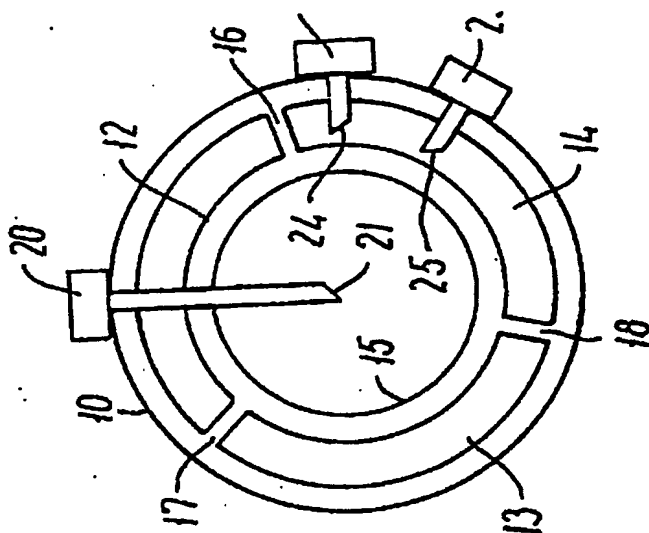


FIG. 4

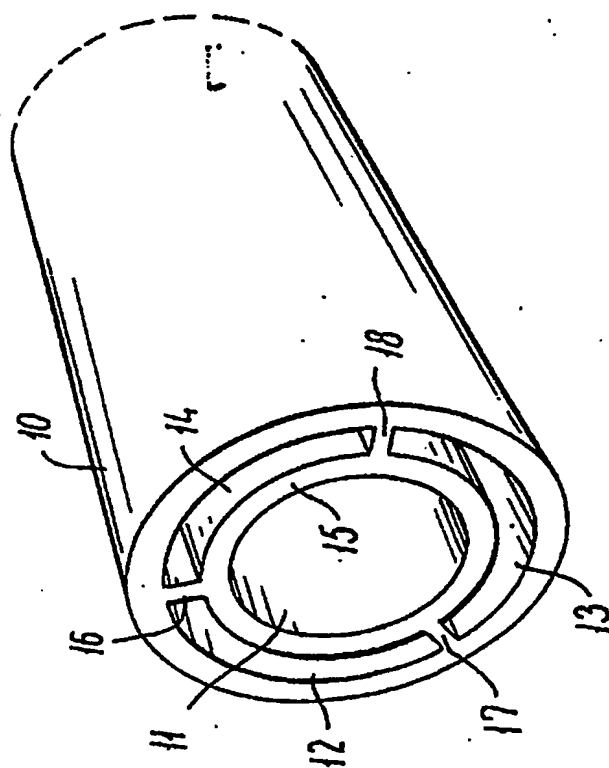


FIG. 3

19 NOV. 2002

Modtaget

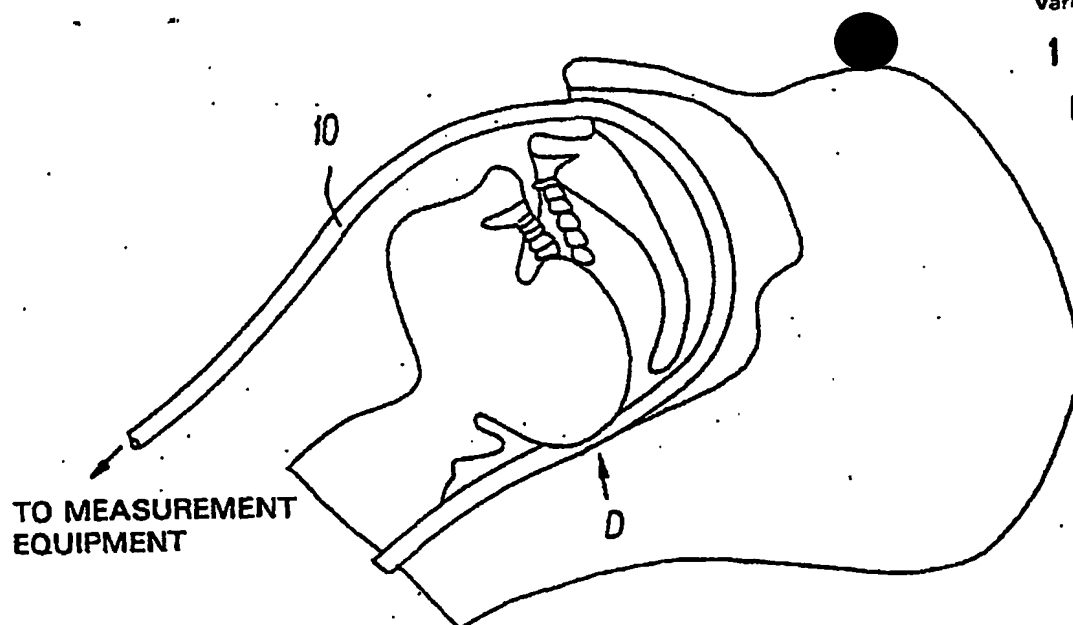


FIG. 5

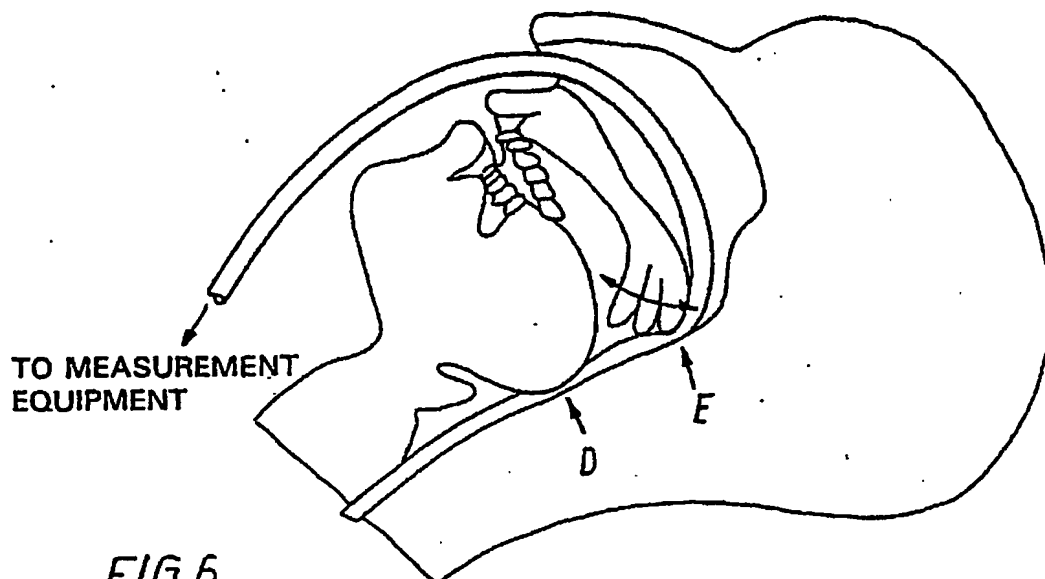


FIG. 6

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.